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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/948,149	10/09/1997	BRIAN M. FENDLY	P1053R2	6683
24510	7590	11/30/2006	EXAMINER	
DLA PIPER US LLP ATTN: PATENT GROUP 1200 NINETEENTH STREET, NW WASHINGTON, DC 20036			SWARTZ, RODNEY P	
			ART UNIT	PAPER NUMBER
			1645	

DATE MAILED: 11/30/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

08/948,149

Applicant(s)

FENDLY ET AL.

Examiner

Rodney P. Swartz, Ph.D.

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 March 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 28-40 and 42-65 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 28-40 and 42-65 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 1 March 2006 has been entered.

Claim 63 has been amended. New claim 65 has been entered.

2. Claims 28-40 and 42-65 are pending and under consideration.

Rejections Withdrawn

3. The rejection of claim 64 under 35 U.S.C. 112, second paragraph, lack of antecedent basis for the limitation "the method of claim 63 wherein said second anti-ErbB2 antibody" in line 1 is withdrawn in light of the amendment of claim 63.

Rejections Maintained

4. The rejection of claims 28-31, 37, 38, 40, 56, and 57 under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Shepard et al (*J. Clin. Immunol.*, 11(3):117-127, 1991) is maintained for reasons of record.

Applicants argue that Shepard et al does not provide an enabling disclosure because it does not disclose sufficient guidance/information for a skilled person to reproduce these particular antibodies. In addition, applicants argue that the claimed antibodies were not publicly available at the time of filing of the instant application.

Applicants' arguments have been considered, but have not been found persuasive.

M.P.E.P. §2133.03(a) [R-5] "Public Use" recites:

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I. **> TEST FOR "PUBLIC USE

The public use bar under 35 U.S.C. 102(b) arises where the invention is in public use before the critical date and is ready for patenting. *Invitrogen Corp. v. Biocrest Manufacturing L.P.*, 424 F.3d 1374, 76 USPQ2d 1741 (Fed. Cir. 2005). As explained by the court,

The proper test for the public use prong of the § 102 (b) statutory bar is whether the purported use: (1) was accessible to the public; or (2) was commercially exploited. Commercial exploitation is a clear indication of public use, but it likely requires more than, for example, a secret offer for sale. Thus, the test for the public use prong includes the consideration of evidence relevant to experimentation, as well as, *inter alia*, the nature of the activity that occurred in public; public access to the use; confidentiality obligations imposed on members of the public who observed the use; and commercial exploitation.... That evidence is relevant to discern whether the use was a public use that could raise a bar to patentability, but it is distinct from evidence relevant to the ready for patenting component of Pfaff's two-part test, another necessary requirement of a public use bar *Id.* at 1380, 76 USPQ2d at 1744 (citations omitted). See MPEP § 2133.03(c) for a discussion of the "ready for patenting" prong of the public use and on sale statutory bars.<

"[T]o constitute the public use of an invention it is not necessary that more than one of the patent articles should be publicly used. The use of a great number may tend to strengthen the proof, but one well defined case of such use is just as effectual to annul the patent as many." Likewise, it is not necessary that more than one person use the invention. *Egbert v. Lippmann*, 104 U.S. 333, 336 (1881).

II. PUBLIC KNOWLEDGE IS NOT NECESSARILY PUBLIC USE UNDER 35

U.S.C. 102(b)

Mere knowledge of the invention by the public does not warrant rejection under 35 U.S.C. 102(b). 35 U.S.C. 102(b) bars public use or sale, not public knowledge. *TP Labs., Inc., v. Professional Positioners, Inc.*, 724 F.2d 965, 970, 220 USPQ 577, 581 (Fed. Cir. 1984).

Note, however, that public knowledge may provide grounds for rejection under 35 U.S.C. 102(a). See MPEP § 2132.

A. Commercial Versus Noncommercial Use and the Impact of Secrecy

> There are limited circumstances in which a secret or confidential use of an invention may give rise to the public use bar. "[S]ecrecy of use alone is not sufficient to show that existing knowledge has not been withdrawn from public use; commercial exploitation is also forbidden." *Invitrogen*, 424 F.3d at 1382, 76 USPQ2d at 1745-46 (The fact that patentee secretly used the claimed invention internally before the critical date to develop future products that were never sold was by itself insufficient to create a public use bar to patentability.).<

1. "Public Use" and "Non-secret Use" Are Not Necessarily Synonymous

"Public" is not necessarily synonymous with "non- secret." The fact "that non-secret uses of the device were made [by the inventor or someone connected with the inventor] prior to the critical date is not itself dispositive of the issue of whether activity barring a patent under 35 U.S.C. 102(b) occurred. The fact that the device was not hidden from view may make the use not secret, but nonsecret use is not ipso facto public use' activity. Nor, it must be added, is all secret use ipso facto not public use' within the meaning of the statute," if the inventor is making commercial use of the invention under circumstances which preserve its secrecy. *TP Labs., Inc. v. Professional Positioners, Inc.*, 724 F.2d 965, 972, 220 USPQ 577, 583 (Fed. Cir. 1983) (citations omitted).

2. Even If the Invention Is Hidden, Inventor Who Puts Machine or Article Embodying the Invention in Public View Is Barred from Obtaining a Patent as the Invention Is in Public Use

When the inventor or someone connected to the inventor puts the invention on display or sells it, there is a "public use" within the meaning of 35 U.S.C. 102(b) even though by its very nature an invention is completely hidden from view as part of a larger machine or article, if the invention is otherwise used in its natural and intended way and the larger machine or article is accessible to the public. *In re Blaisdell*, 242 F.2d 779, 783, 113 USPQ 289, 292 (CCPA 1957); *Hall v. Macneale*, 107 U.S. 90, 96-97 (1882); *Ex parte Kuklo*, 25 USPQ2d 1387, 1390 (Bd. Pat. App. & Inter. 1992) (Display of equipment including the structural features of the claimed invention to visitors of laboratory is public use even though public did not see inner workings of device. The person to whom the invention is publicly disclosed need not understand the significance and technical complexities of the invention.).

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3. There Is No Public Use If Inventor Restricted Use to Locations Where There Was a Reasonable Expectation of Privacy and the Use Was for His or Her Own Enjoyment
An inventor's private use of the invention, for his or her own enjoyment is not a public use. *Moleculon Research Corp. v. CBS, Inc.*, 793 F.2d 1261, 1265, 229 USPQ 805, 809 (Fed. Cir. 1986) (Inventor showed inventive puzzle to close friends while in his dorm room and later the president of the company at which he was working saw the puzzle on the inventor's desk and they discussed it. Court held that the inventor retained control and thus these actions did not result in a "public use.").

4. The Presence or Absence of a Confidentiality Agreement is Not Dispositive of the Public Use Issue

"The presence or absence of a confidentiality agreement is not dispositive of the public use issue, but is one factor to be considered in assessing all the evidence." *Bernhardt, L.L.C. v. Collezione Europa USA, Inc.*, 386 F.3d 1371, 1380-81, 72 USPQ2d, 1901, 1909 (Fed. Cir. 2004) (quoting *Moleculon Research Corp. v. CBS Inc.*, 793 F.2d 1261, 1266, 229 USPQ 805, 808 (Fed. Cir. 1986)). The court stressed that it is necessary to analyze the **>evidence of public use in the context of < policies that underlie the public use and on sale bar that include "discouraging removal of inventions from the public domain that the public justifiably believes are freely available, prohibiting an extension of the period for exploiting an invention, and favoring prompt and widespread disclosure of inventions." *Bernhardt*, 386 F.3d at 1381, 72 USPQ2d at 1909. See also > *Invitrogen*, 424 F.3d at 1379, 76 USPQ2d at 1744; < MPEP § 2133.03, Policy Considerations. **>Evidence< that the court emphasized included the "nature of the activity that occurred in public; the public access to and knowledge of the public use; [and] whether there were any confidentiality obligations imposed on persons who observed the use." *Bernhardt*, 386 F.3d at 1381, 72 USPQ2d at 1909. For example, the court in *Bernhardt* noted that an exhibition display at issue in the case "was not open to the public, that the identification of attendees was checked against a list of authorized names by building security and later at a reception desk near the showroom, that attendees were escorted through the showroom, and that the attendees were not permitted to make written notes or take photographs inside the showroom." *Id.* The court remanded the issue of whether the exhibition display was a public use for further proceedings since the district court "focused on the absence of any confidentiality agreements and did not discuss or analyze how the totality of the circumstances surrounding" the exhibition "comports with the policies underlying the public use bar." *Id.*

B. Use by Third Parties Deriving the Invention from Applicant

An Invention Is in Public Use If the Inventor Allows Another To Use the Invention Without Restriction or Obligation of Secrecy

"Public use" of a claimed invention under 35 U.S.C. 102(b) occurs when the inventor allows another person to use the invention without limitation, restriction or obligation of secrecy to the inventor." *In re Smith*, 714 F.2d 1127, 1134, 218 USPQ 976, 983 (Fed. Cir. 1983). The presence or absence of a confidentiality agreement is not itself determinative of the public use issue, but is one factor to be considered along with the time, place, and circumstances of the use which show the amount of control the inventor retained over the invention. *Moleculon Research Corp. v. CBS, Inc.*, 793 F.2d 1261, 1265, 229 USPQ 805, 809 (Fed. Cir. 1986). See *Ex parte C*, 27 USPQ2d 1492, 1499 (Bd. Pat. App. & Inter. 1992) (Inventor sold inventive soybean seeds to growers who contracted and were paid to plant the seeds to increase stock for later sale. The commercial nature of the use of the seed coupled with the "on-sale" aspects of the contract and apparent lack of confidentiality requirements rose to the level of a "public use" bar.); *Egbert v. Lippmann*, 104 U.S. 333, 336 (1881) (Public use found where inventor allowed another to use inventive corset insert, though hidden from view during use, because he did not impose an obligation of secrecy or restrictions on its use.).

C. Use by Independent Third Parties

Use by an Independent Third Party Is Public Use If It Sufficiently "Informs" the Public of the Invention or a Competitor Could Reasonably Ascertain the Invention

Any "nonsecret" use of an invention by someone unconnected to the inventor, such as someone who has independently made the invention, in the ordinary course of a business for trade or profit may be a "public use," *Bird Provision Co. v. Owens Country Sausage, Inc.*, 568 F.2d 369, 374-76, 197 USPQ 134, 138-40 (5th Cir. 1978).

Additionally, even a "secret" use by another inventor of a machine or process to make a product is "public" if the details of the machine or process are ascertainable by inspection or analysis of the product that is sold or publicly displayed. *Gillman v. Stern*, 114 F.2d 28, 46 USPQ 430 (2d Cir. 1940); *Dunlop Holdings, Ltd. v. Ram Golf Corp.*, 524

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F.2d 33, 36-7, 188 USPQ 481, 483-484 (7th Cir. 1975). If the details of an inventive process are not ascertainable from the product sold or displayed and the third party has kept the invention as a trade secret then that use is not a public use and will not bar a patent issuing to someone unconnected to the user. *W.L. Gore & Assocs. v. Garlock, Inc.*, 721 F.2d 1540, 1550, 220 USPQ 303, 310 (Fed. Cir. 1983). However, a device qualifies as prior art if it places the claimed features in the public's possession before the critical date even if other unclaimed aspects of the device were not publicly available. *Lockwood v. American Airlines, Inc.*, 41 USPQ2d 1961, 1964-65 (Fed. Cir. 1997) (Computer reservation system was prior art even though "essential algorithms of the SABRE software were proprietary and confidential and...those aspects of the system that were readily apparent to the public would not have been sufficient to enable one skilled in the art to duplicate the [unclaimed aspects of the] system."). The extent that the public becomes "informed" of an invention involved in public use activity by one other than an applicant depends upon the factual circumstances surrounding the activity and how these comport with the policies underlying the on sale and public use bars. *Manville Sales Corp. v. Paramount Sys., Inc.*, 917 F.2d 544, 549, 16 USPQ2d 1587, 1591 (Fed. Cir. 1990) (quoting *King Instrument Corp. v. Otari Corp.*, 767 F.2d 833, 860, 226 USPQ 402, 406 (Fed. Cir. 1985)). By way of example, in an allegedly "secret" use by a third party other than an applicant, if a large number of employees of such a party, who are not under a promise of secrecy, are permitted unimpeded access to an invention, with affirmative steps by the party to educate other employees as to the nature of the invention, the public is "informed." *Chemithon Corp. v. Proctor & Gamble Co.*, 287 F. Supp. 291, 308, 159 USPQ 139, 154 (D.Md. 1968), aff'd, 427 F.2d 893, 165 USPQ 678 (4th Cir. 1970).

Even if public use activity by one other than an applicant is not sufficiently "informing," there may be adequate grounds upon which to base a rejection under 35 U.S.C. 102(f) and 35 U.S.C. 102(g). See *Dunlop Holdings Ltd. v. Ram Golf Corp.*, 524 F.2d 33, 188 USPQ 481 (7th Cir. 1975). See MPEP § 2137 and § 2138.

2133.03(b) [R-5] "On Sale"

An impermissible sale has occurred if there was a definite sale, or offer to sell, more than 1 year before the effective filing date of the U.S. application and the subject matter of the sale, or offer to sell, fully anticipated the claimed invention or would have rendered the claimed invention obvious by its addition to the prior art. *Ferag AG v. Quipp, Inc.*, 45 F.3d 1562, 1565, 33 USPQ2d 1512, 1514 (Fed. Cir. 1995). The on-sale bar of 35 U.S.C. 102(b) is triggered if the invention is both (1) the subject of a commercial offer for sale not primarily for experimental purposes and (2) ready for patenting. *Pfaff v. Wells Elecs., Inc.*, 525 U.S. 55, 67, 48 USPQ2d 1641, 1646-47 (1998). Traditional contract law principles are applied when determining whether a commercial offer for sale has occurred. See *Linear Tech. Corp. v. Micrel, Inc.*, 275 F.3d 1040, 1048, 61 USPQ2d 1225, 1229 (Fed. Cir. 2001), petition for cert. filed, 71 USLW 3093 (Jul. 03, 2002) (No. 02-39); *Group One, Ltd. v. Hallmark Cards, Inc.*, 254 F.3d 1041, 1047, 59 USPQ2d 1121, 1126 (Fed. Cir. 2001) ("As a general proposition, we will look to the Uniform Commercial Code (UCC) to define whether ... a communication or series of communications rises to the level of a commercial offer for sale.").

Thus, according to this section, the proper test for the public use prong of the § 102 (b) statutory bar is whether the purported use: (1) was accessible to the public; or (2) was commercially exploited. The presence of a Material Transfer Agreement constitutes "accessibility" to the public.

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5. The rejection of claims 28-31, 37, 38, and 40 under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Lewis et al (*Cancer Immunol. Immunother.*, 37:255-263, 1993) is maintained for reasons of record.

Applicants argue that Lewis et al does not provide an enabling disclosure because it does not disclose sufficient guidance/information for a skilled person to reproduce these particular antibodies. In addition, applicants argue that the claimed antibodies were not publicly available at the time of filing of the instant application.

Applicants' arguments have been considered, but have not been found persuasive for the same reasoning as put forth in the Shepard et al rejection response, *supra*.

6. The rejection of claims 32-36, 39, and 58 under 35 U.S.C. 103(a) as being unpatentable over Shepard et al (*J. Clin. Immunol.*, 11(3):117-127, 1991), or Lewis et al (*Cancer Immunol. Immunother.*, 37:255-263, 1993), in view of Fendly et al (*Cancer Research*, 50:1550-1558, 1990), Deshane et al (*J. Invest. Med.*, 43(Suppl. 2):328A, 1995), and further in view of Senter et al (U.S. Pat. No. 4,975,278) is maintained for reasons of record.

Applicants argue that none of the cited references provide an enabling disclosure because it does not disclose sufficient guidance/information for a skilled person to reproduce these particular antibodies. In addition, applicants argue that the claimed antibodies were not publicly available at the time of filing of the instant application.

Applicants' arguments have been considered, but have not been found persuasive for the same reasoning as put forth in the Shepard et al rejection response, *supra*.

7. The rejection of claims 42-55 and 59-62 under 35 U.S.C. 103(a) as being unpatentable over Shepard et al (*J. Clin. Immunol.*, 11(3):117-127, 1991) in view of Lewis et al (*Cancer Immunol. Immunother.*, 37:255-263, 1993) and Fendly et al (*Cancer Research*, 50:1550-1558,

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1990), and further in view of Deshane et al (*J. Invest. Med.*, 43(Suppl. 2):328A, 1995), and Senter et al (U.S. Pat. No. 4,975,278) is maintained for reasons of record.

Applicants argue that none of the cited references provide an enabling disclosure because it does not disclose sufficient guidance/information for a skilled person to reproduce these particular antibodies. In addition, applicants argue that the claimed antibodies were not publicly available at the time of filing of the instant application.

Applicants' arguments have been considered, but have not been found persuasive for the same reasoning as put forth in the Shepard et al rejection response, *supra*.

8. The rejection of claim 63 under 35 U.S.C. 102(b) as being anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Shepard et al (*J. Clin. Immunol.*, 11(3):117-127, 1991) is maintained for reasons of record.

Applicants argue that none of the cited references provide an enabling disclosure because it does not disclose sufficient guidance/information for a skilled person to reproduce these particular antibodies. In addition, applicants argue that the claimed antibodies were not publicly available at the time of filing of the instant application.

Applicants' arguments have been considered, but have not been found persuasive for the same reasoning as put forth in the Shepard et al rejection response, *supra*.

9. The rejection of claim 63 under 35 U.S.C. 102(b) as being anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Lewis et al (*Cancer Immunol. Immunother.*, 37:255-263, 1993) is maintained for reasons of record.

Applicants argue that none of the cited references provide an enabling disclosure because it does not disclose sufficient guidance/information for a skilled person to reproduce

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these particular antibodies. In addition, applicants argue that the claimed antibodies were not publicly available at the time of filing of the instant application.

Applicants' arguments have been considered, but have not been found persuasive for the same reasoning as put forth in the Shepard et al rejection response, *supra*.

10. The rejection of claim 64 under 35 U.S.C. 103(a) as being unpatentable over Shepard et al (*J. Clin. Immunol.*, 11(3):117-127, 1991), or Lewis et al (*Cancer Immunol. Immunother.*, 37:255-263, 1993), in view of Fendly et al (*Cancer Research*, 50:1550-1558, 1990) is maintained for reasons of record.

Applicants argue that none of the cited references provide an enabling disclosure because it does not disclose sufficient guidance/information for a skilled person to reproduce these particular antibodies. In addition, applicants argue that the claimed antibodies were not publicly available at the time of filing of the instant application.

Applicants' arguments have been considered, but have not been found persuasive for the same reasoning as put forth in the Shepard et al rejection response, *supra*.

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. Claim 65 is rejected under 35 U.S.C. 103(a) as being unpatentable over Shepard et al (*J. Clin. Immunol.*, 11(3):117-127, 1991), or Lewis et al (*Cancer Immunol. Immunother.*, 37:255-263, 1993), in view of Fendly et al (*Cancer Research*, 50:1550-1558, 1990).

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Claim 65 is drawn to a method for inducing cell death in a patient, comprising exposing a cell which overexpresses ErbB2 to an effective amount of an isolated antibody that binds to an epitope on ErbB2 to which antibody 7C2 binds by administration to said patient a pharmaceutical composition comprising an active agent consisting of an antibody which binds to a epitope on ErbB2 to which antibody 7C2 binds.

Claim 64 utilizes the open language "comprising" in delineating the methods steps. Such language encompasses induction of apoptosis which is taught in the instant specification as one of the mechanisms by which the claimed antibody induces cell death, but the scope of the claim is not restricted only to apoptosis, nor is the language restricted as to the use of other reagents, such a complement, phagocytic cells, cytotoxic drugs, or growth inhibitory agents, in addition to the antibody. The specification teaches that antibodies 7C2 and 7F3 bind to Domain 1 of ErbB2 and that antibody 4D5 binds to ErbB2, but not to Domain 1.

Shepard et al teach monoclonal anti-HER2 antibodies 7C2 and 7F3 which bind to Domain 1 of ErbB2 (Fig. 2; page 119, section **Derivation of muMab 4D5**) and which inhibit SKBR3 proliferation by 21% and 38% respectively (Table II).

Lewis et al teach monoclonal anti-HER2 monoclonal antibodies, e.g., 4D5, 7C2, and 7F3, which inhibit human tumor cells such SKBR3 (Table 2) and mediate antibody-dependent cellular cytotoxicity (Figure 4).

Fendly et al teach the production and characterization of the monoclonal anti-HER2 antibodies utilized by Shepard et al and Lewis et al (Abstract; page 1550-1552, section **Materials and Methods**).

Thus, it would have been obvious at the time the invention was made to a person having ordinary skill in the art to use anti-HER2 antibodies which bind to various epitopes on

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ErbB2, such as 4D5, 7C2, and 7F3 as taught Shepard et al, Lewis et al, and Fendly et al to induce cell death in a cell *in vivo* which overexpresses ErbB2.

Conclusion

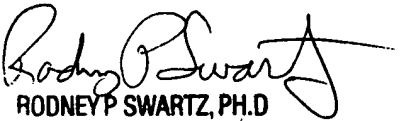
13. No claims are allowed.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rodney P. Swartz, Ph.D., Art Unit 1645, whose telephone number is (571) 272-0865. The examiner can normally be reached on Monday through Thursday from 5:30 AM to 4:00 PM EST.

If attempts to reach the Examiner by telephone are unsuccessful, the examiner's Supervisor, Jeffrey Siew, can be reached on (571)272-0787.

The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


RODNEY P. SWARTZ, PH.D.
PRIMARY EXAMINER
Art Unit 1645

November 27, 2006